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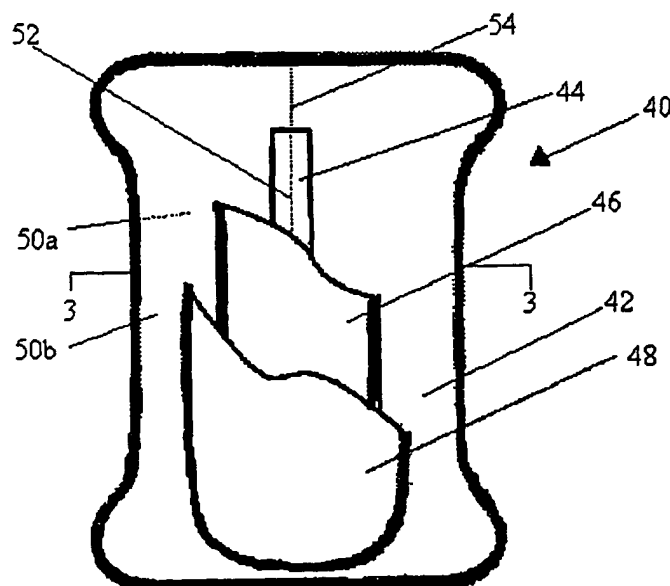
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(54) Title: DISPOSABLE SELF-ADHESIVE FOOT PATCH FOR ANATOMICAL SUPPORT TO THE MIDFOOT AREA



(57) Abstract: A disposable self-adhesive foot patch (40) having breathability that is adhesively applied to the foot for anatomical support to prevent and reduce fatigue and discomfort in the feet, legs, and lower limbs.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## DISPOSABLE SELF-ADHESIVE FOOT PATCH FOR ANATOMICAL SUPPORT TO THE MIDFOOT AREA

This application is a continuation-in-part of International PCT Application No. PCT/00/32541 filed November 29, 2000 in the United States Receiving Office and claims priority to that application.

### FIELD OF THE INVENTION

The present invention relates to a disposable self-adhesive foot patch for application to the midfoot area. Specifically, the present invention relates to a disposable self-adhesive foot patch that provides anatomical support to the midfoot area to prevent and reduce fatigue and discomfort in the feet and legs.

### BACKGROUND OF THE INVENTION

During each footfall in walking, forces are acting between the ground and the foot. These forces are usually referred to as ground reaction forces (GRF). They can be quantified using appropriate measuring devices. The order of magnitude of GRF for walking is 1 to 1.5 times a person's body weight. Studies have shown that there are typically two distinct phases of force when there is foot-ground interaction. First is when the foot collides with the ground and second is when the foot pushes off from the ground. The two phases of force have different consequences with respect to the human musculoskeletal system.

Foot devices have covered a broad range of materials and structures to help distribute the forces acting on the foot during a normal gait cycle. Such devices can be a padded flat surface or shaped to conform to the foot. When conformed to the foot, devices can be custom made to conform to a particular foot or devices can be made to fit to an average foot.

Custom shaped foot devices tend to be made from durable, rigid material that is designed to be worn every day. These devices tend to be expensive and require modification subsequent to fitting. Additionally custom devices are typically bulky and require replacement when the size of the foot changes. An example of such a device is shown in U.S. Pat. No. 4,360,027.

Other foot devices have been made from materials that deform under pressure. Such devices are exemplified by U.S. Pat. No. 6,138,383. These foot

devices are designed for extended use in a person's footwear. These devices take the shape of a shoe insert covering either the entire bottom of the foot or some smaller area thereof.

Typically shoe inserts have difficulties in maintaining a cushioning and structural support for extended periods of time. The inserts can be bulky and make shoes uncomfortable to the foot. The inserts are subject to unsanitary conditions inside of the shoe environment including bacteria, dirt, sweat and odors. Also, these inserts cannot be used with all types of footwear, especially footwear that does not have an entirely enclosed construction such as sandals and some women's shoes. However, even devices that can be worn in sandals and other open shoe structures, still pose problems with the sweat produced by the foot.

The average human foot produces between 200 mL to 500 mL of moisture a day. Thus, the humidity within a shoe can be quite high. If an item is adhesively placed on the skin, the skin becomes wet and overhydration can occur. This affects the skin of the wearer and the adhesive properties of the item placed onto the skin of the foot. The addition of the frictional forces produced by walking, a product adhesively applied to the foot will have a tendency to peel off or migrate during movement.

Skin occlusion can negatively impact comfort and cause negative changes to skin structure. Skin overhydration can be a common problem in products that are attached to the skin. This can increase the chance of skin irritation and skin softening (maceration). As a result of maceration, the skin is more subject to abrasion due to normal movement, and skin disorders such as erythema (i.e. redness), heat rash, abrasion, pressure marks and skin barrier loss.

Such problems have been addressed with medical dressings. Patches or pads that attach directly to the skin are well known in the medical industry for wound dressings. While these types of bandages address the breathability issues (i.e. vapor permeability), they lack the anatomical structural support necessary for a foot device.

Another property of medical wound dressings is liquid absorption. Often medical wound dressings are designed to absorb fluids that emanate from the wound. Similarly, in the foot area, sweat glands produce enough fluid to result in maceration of the skin. A disposable article that can absorb some of the sweat

produced by the foot is desirable. However, medical wound dressings are designed to absorb and hold bodily fluids. This type of design is undesirable for foot devices since the area available in a wearer's shoe is limited and an increase in volume of the foot device can cause discomfort. Therefore it is desirable to have an absorption layer included in the disposable self-adhesive foot patch that acts more for wicking purposes and allows for the incremental release of sweat after it is absorbed.

Patches or pads that attach directly to the foot have been disclosed previously. Exemplary are JP Pat. No. 8-98868A (Kokai) which discloses an adhesive arch support, JP Pat. No. 11-255635A (Kokai) which discloses adhesive foot patches for stimulating reflex points, and U.S. Pat. No. 6,120,473 which discloses an adhesive arch support. These references fail to address the important problem of foot wetness. As such, these devices can lead to foot discomfort if worn for an extended period of time. These devices do not provide a wicking element to remove the sweat from the foot to be transported away from the skin of the foot that can also alleviate overhydration problems. Also, these devices suggest solely foam material to the arch area that may not provide satisfying anatomical structural support for the arch area.

Accordingly, the need exists for a disposable device that provides adequate anatomical structural support for the foot area that can be applied directly or indirectly to the skin and that is breathable to allow vapor permeability and liquid permeability.

## SUMMARY

The present invention relates to a disposable self-adhesive foot patch comprising an adherent article having a first and second side wherein the adherent article has an MVTR value of at least 200 g/24 h/ m<sup>2</sup> and the first side of the adherent article being provided with an adhesive; and a resilient ridge having an elongated shape with a major and a minor axis, the resilient ridge being connected to the second side of the adherent article; wherein first side of the adherent article is placed against the midfoot area and adhered thereto by the adhesive. The present invention also relates to a disposable self-adhesive foot patch comprising an adherent article having a first and second side wherein the adherent article has an MVTR value of at least 200 g/24 h/ m<sup>2</sup>; the first side of the adherent article being provided with an adhesive; and a resilient ridge having an elongated shape with a major and a minor axis superposed over the first side of the adherent article wherein the resilient ridge is placed against the midfoot area and adhered thereto by the adhesive provided on the first side of the adherent article.

It has now been found that the present invention can provide anatomical support to the midfoot to prevent and reduce fatigue and discomfort in the foot and leg areas more effectively than traditional noncustomized foot devices. The present invention allows the wearer to position the foot device in a position to provide the greatest benefit to the wearer. The present invention also allows the wearer to select the properties they are most interested in using.

The present invention is designed to be disposable to address the unsanitary conditions often found in permanent inserts. The present invention may be attached to the foot so as to not restrict the use to closed shoe structures. The disposable self-adhesive foot patch can provide anatomical support with or without footwear. The ability of the disposable self-adhesive foot patch to deliver anatomical support is derived from the wearer being able to place an effective material to the desired portion of the foot. The wearer is able to place, for example, a longitudinal arch support in a position that is most effective to the wearer without having the disposable self-adhesive foot patch specifically fitted to the wearer's foot. The present invention is breathable to avoid the moisture problems associated with the foot area. The present invention may also be clear or skin-toned in appearance to address concerns

over discreetness in wearing foot devices that are visible when the person has open footwear or no footwear. Additionally, the present invention is light in weight to allow comfortable wearing in footwear and to reduce fatigue than can result from heavier foot devices.

These and other features, aspects, advantages, and variations of the present invention, and the embodiments described herein, will become evident to those skilled in the art from a reading of the present disclosure with the appended claims, and are covered within the scope of these claims.

### BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with claims particularly pointing out and distinctly claiming the invention, it is believed that the invention will be better understood from the following description of the accompanying drawings, not necessarily drawn to scale, in which:

Fig. 1 shows a top view of a human foot skeletal structure without the phalanges shown;

Fig. 2 is a partial cut away top view of a preferred embodiment of the disposable self-adhesive foot patch of the present invention; and

Fig. 3 is a sectional side view of a preferred embodiment of Fig. 1 taken along section line 3-3.

### DETAILED DESCRIPTION OF THE INVENTION

All percentages, ratios and proportions herein are by weight of the final composition, unless otherwise specified. All temperatures are in degrees Celsius (°C) unless otherwise specified. All documents cited are incorporated herein by reference in their entireties. Citation of any reference is not an admission regarding any determination as to its availability as prior art to the claimed invention.

The term "disposable" is used herein to describe articles that are not intended to be laundered or otherwise restored or reused as an article (i.e. they are intended to be discarded after a single use and, preferably, to be recycled, composted or otherwise disposed of in an environmentally compatible manner.)

The term "anatomical support" refers to skeletal and/or muscular support received from the present invention including, but not limited to cushioning, shock absorption, and bracing properties.

When the foot collides with the ground, the heel of the foot, for about 80% of individuals, strikes the ground first. After the impact of the heel striking the ground, a normal human gait continues on to a second phase of force that occurs when the foot pushes off from the ground. The second phase affects the medial longitudinal arch (MLA) (20) of the foot shown highlighted in Fig. 1. The arch area of the foot provides the elastic, springy connection between the forefoot and the hindfoot areas. The skeletal structure of the arch along with ligaments provides integrity to the arch area. The plantar calcaneonavicular ligament, sometimes called the spring ligament (22) is the main support for the MLA. The navicular (24) which communicates with the head of the talus (26) and all three cuneiform bones (28a, 28b, 28c); it is the attachment site for the spring ligament. The spring ligament provides some elasticity and springiness to the arch. The spring ligament stretches and contracts dependent upon what portion of the gait that the foot is currently undertaking. The stretching of the spring ligament corresponds to a foot position called supination. The contraction of the spring ligament corresponds to a foot position called pronation. The general order of the foot motion is summarized below.

Table 1

	Heel Impact	Flat Foot Stance	Ball of Foot	Off Ground
Foot position	Supinated	Pronated	Supinated	Pronated

While this process is a normal part of a human gait, excessive pronation or eversion is the source of many lower extremity pathologies, including muscle fatigue and inflammation, foot and knee joint pain, tendinitis, ligament strain, and even neurological damage. Excessive pronation or eversion also renders the gait less efficient since time and effort is wasted in pronating and supination.

The disposable self-adhesive foot patch of the present invention may be used to alleviate the problems described above, while not being limited by a theory, by attempting to mimic the function of the spring ligament in the MLA..

#### THE DISPOSABLE SELF-ADHESIVE FOOT PATCH

The disposable self-adhesive foot patch (40), shown in Figs. 2 and 3, comprises an adherent article (42), a resilient ridge (44), a shaping material (46),



and an enclosing member (48). The adherent article (42) is preferably a generally rectangular or "I" shape. The adherent article (42) has a first side (50a) and a second side (50b). The first side (50a) of the adherent article (42) has an adhesive coated on its surface (not shown). The resilient ridge (44) is preferably an elongated tubular structure. The resilient ridge (44) is superposed over the center of the on the second side (50b) of the adherent article (42). The resilient ridge (44) is superposed over the adherent article (42) so that the major axis (52) of the resilient ridge (44) corresponds to the major axis (54) of the adherent article (42).

The shaping material (46) comprises a shaping material first side (56a) and a shaping material second side (56b), see Fig. 3. The shaping material first side (56a) is superposed over the resilient ridge (44) and comes into contact with the adherent article (42) on the second side (50b) of the adherent article (42). The enclosing member (48) surrounds the shaping material (46) on the shaping material second side (56b) and attaches to the first side (50a) of the adherent article (42).

The first side (50a) of the adherent article (42) is attached directly to the midfoot area, preferably located in the area corresponding to the navicular (24), to either side of the spring ligament (22).

The disposable self-adhesive foot patch according to the present invention should be light in weight. The disposable self-adhesive foot patch should be between 100 grams to 0.0001 grams, preferably between 50 grams and 0.0001 grams, and most preferably between 15 grams and 0.0001 grams.

#### ADHERENT ARTICLE

Numerous disclosures are directed to improving wearer skin condition by reducing the risk of creating overhydrated skin or by allowing already overhydrated skin to dehydrate to a level closer to unoccluded skin when an adherent article (42) is applied to or near the skin. Water molecules are continuously escaping from unoccluded skin into the surrounding air. However, the placement of an article near or on the skin allows the relative humidity near the surface of the skin to be close to 100%. Air is still present around the skin but essentially there is no loss water from the skin to the surrounding air, that is, water molecules leave the skin for the air at about the same rate as water

molecules absorb into the skin from the air. The accumulation of moisture creates the overhydration in the skin.

More or less breathable devices or materials are described in U.S. Pat. Nos. 4,627,847, 4,648,876, 4,578,069, 4,713,068, 4,758,339, 4,833,172, 4,923,650, 5,254,111, 5,492,751, 5,599,420 and 5,628,737, in published European Patent applications EP 315,013 and EP 710,471, and in published PCT applications WO 95/16,562 and WO 95/16,746. Generally, all such devices or materials balance gas permeability and liquid impermeability. This becomes particularly apparent when considering materials having apertures or pores, whereby an increase in pore size will allow easier gas permeation, but also easier liquid permeation. Other approaches are aimed at keeping only part of the article breathable, by a part being covered by non-breathable material, but having other parts of the article made of breathable materials.

The adherent article (42) preferably provides adhesive properties that allow the foot patch to applied to the skin under walking conditions but relatively easy to remove after use with gas and liquid permeability to prevent overhydration of the skin.

The adherent article (42) is preferably compliant, soft feeling, and non-irritating to the wearer's skin. Further, the adherent article (42) may be liquid permeable, permitting liquid to readily penetrate through its thickness. A suitable adherent article (42) may be manufactured from a wide range of materials such as woven and nonwoven materials (i.e., a nonwoven web of fibers); polymeric materials such as apertured formed thermoplastic films, apertured plastic films, and hydroformer thermoplastic films; porous foams; reticulated foams; reticulated thermoplastic films; and thermoplastic scrims. Suitable woven and nonwoven materials can comprise natural fibers (e.g., wood or cotton fibers), synthetic fibers (e.g., polymeric fibers such as polyester, polypropylene, or polyethylene fibers) or from a combination of natural and synthetic fibers. When the adherent article (42) comprises a nonwoven web, the web may be manufactured by a wide number of known techniques. For example, the web may be spunbonded, carded, wet-laid, melt-blown, hydroapertured, hydroentangled, combinations of the above, or the like. Such nonwoven webs may be bonded using means known to the art, such as chemical bonding, latex bonding, thermal bonding, and the like. The adherent article (42) of the present

invention may comprise a single layer or it may comprise more than one layer or material.

The adherent article (42) may be coated on the surface or impregnated into the adherent article (42) with any suitable adhesive. A suitable adhesive is an adhesive that gives the requisite degree of adhesion and which is non-toxic and non-allergenic. The adhesive may or may not be vapor permeable. Ideally, the degree of adhesion should be such that the disposable self-adhesive foot patch remains in place for the duration of the user's use. The disposable self-adhesive foot patch should be relatively easily removable at the end of the use.

An essential element of the present invention is the use of materials that are sufficiently permeable to gases, such as air, water vapor, or other volatile materials. Apart from diffusion, gases or vapor can pass through a solid material by small capillary transport (slow), or convective transport (fast). Permeability can be assessed by the well-known Mass Vapor Transmission Rate (MVTR), expressed in units of  $\text{g}/24 \text{ h}/\text{m}^2$  under various driving forces. For purposes of the present invention, the method, as is described in the TEST METHODS section below, involves calcium chloride, which adsorbs moisture passing through the test specimen that is exposed to an environmental relative humidity of 75% at 40°C. An alternative method of assessing gas permeability uses an air permeability test (also described in the TEST METHODS section below), whereby air is sucked through a test specimen under defined conditions such as a specific pressure drop across the sample. As the air permeability test relates to high penetration rates, it is more applicable to materials allowing convective flow (fast) rather than the diffusional or capillary transport dominated (slow) materials.

A suitable material for use as adherent article (42) for purposes of the present invention has a MVTR value of at least about 200  $\text{g}/24 \text{ h}/\text{m}^2$ . Preferably, the MVTR of adherent article (42) of the present invention is at least about 400  $\text{g}/24 \text{ h}/\text{m}^2$ . More preferably, the MVTR of the adherent article (42) is at least about 500  $\text{g}/24 \text{ h}/\text{m}^2$ . Examples of such materials suitable for use in the present invention include woven and nonwoven fiber materials, apertured polymeric films, porous foams, reticulated foams, reticulated polymeric films, and polymeric scrims that are coated or impregnated with a suitable adhesive.

With respect to the present invention, materials manufactured or treated to be permeable can be classified as follows:

Table 2

MVTR	Permeability Range (g/m <sup>2</sup> /24 h)
non-permeable	up to about 200
low permeability	about 200-500
medium permeability	about 500-1000
high permeability	about 1000-2000
very high permeability	more than about 2000

As noted above, materials with low breathability, that is materials with MVTR values greater than about 200-500 g/24 h/m<sup>2</sup> are effective in allowing transport of moisture vapor from the void space between a wearer's body and the present invention.

The adherent article (42) may be made using a hydrophilic substrate to promote rapid transfer of sweat through the adherent article (42). If the material is hydrophobic, at least the upper surface of the adherent article (42) is treated to be hydrophilic so that liquids will transfer there through more rapidly. This diminishes the likelihood that fluids will flow off the adherent article (42) rather than being drawn through the adherent article (42). The adherent article can be rendered hydrophilic by treating it with a surfactant or silica. Suitable methods for treating the adherent article with a surfactant or silica include spraying the adherent article with the surfactant and/or silica and immersing the material into the surfactant and/or silica.

### RESILIENT RIDGE

The resilient ridge (44) is the primary anatomical structural support in the present invention. The resilient ridge (44) preferably is non-irritating to the wearer's skin and provides the desired properties necessary to provide anatomical support to the wearer. The resilient ridge (44), while not being limited by a theory, is selected to mimic the function of the spring ligament in the MLA. Therefore material that is springy and elastic, but providing some hardness are preferred properties for the resilient ridge (44). The resilient ridge (44) preferably comprises materials such as natural or man-made rubber, silicon or other similar materials. The material of the resilient ridge (44) may comprise a single material or it may comprise more than one material. The shape of the

resilient ridge (44) is preferably an elongated shape having a major and minor axis preferably having a generally tubular structure. When placed on the foot, the major axis of the resilient ridge (44) preferably corresponds to the direction that the spring ligament (22) runs in the foot, and preferably is located to either side of the spring ligament (22).

Preferably the material selected for the resilient ridge (44) has a hardness measurement (IRHD) between about 30 and about 81 as measured according to JIS K6253 (micro type) at 23°C, more preferably between about 35 and about 65. The stiffness of the material for the resilient ridge (44) is preferably between about 1.00 N/mm and about 3.7 N/mm at a stress range of less than 10 kgf/cm<sup>2</sup> as measured according to JIS 6254 with a sample of 50 mm conditioned at an initial load of 0.05 N. Test speed was 5 mm/min and load cell was 25 N. The stiffness test was conducted at 23°C

#### SHAPING MATERIAL

Some users may perceive the resilient ridge (44) as uncomfortable to the midfoot area. As such, a shaping material (46) may further be used to contour the area around the resilient ridge (44) to give a smoother profile to the area around the resilient ridge (44). The shaping material (46) is superpose over the resilient ridge (44) either partially or completely, and is preferably attached to the adherent article (42). The resilient ridge (44) may or may not be attached to the shaping material (46). Exemplary materials for the shaping material (46) include natural and man-made materials such as polymeric foams, gels, laminates, resins, rubbers, or other viscoelastic materials.

There are no purely elastic or purely viscous materials in nature; there is always a combination of these two properties. All materials comprise elastic and viscous properties and are referred to as viscoelastic. A material is considered "elastic" if it is predominantly elastic, i.e. if it has only to small extent viscous properties. On the other hand, a material is "viscous", if it has predominately viscous properties, i.e. only to a small extent elastic properties. Elastic materials store energy, i.e. convert mechanical work into potential energy, which is recoverable. Viscous materials do not store energy, but when stressed dissipate it as heat as they flow. This dissipation gives highly damped motion.

Properties that the shaping material (46) preferably includes adequate reaction to dynamic compression, rebound resiliency, hardness, vertical wicking,

absorbency characteristics such as absorbency under pressure, and vapor permeability.

A) Dynamic Compression

The shaping material (46) preferably has mechanical properties that can be subjected to dynamic compression. The average human gait repeats on a frequency of approximately 1 Hz and any materials attached to the human foot is subjected to the same frequency of force. It is therefore preferable to have a shaping material (46) that has elastic and viscosity properties that can respond to these recurring forces. The elasticity and viscosity of viscoelastic material can be measured under dynamic compression conditions. Preferably the shaping material (46) has a dynamic modulus of elasticity between about  $1.0 \times 10^4$  Pa at 1 Hz and about  $2.65 \times 10^5$  Pa at 1 Hz as measured by JIS K7244-4 described below in TEST METHODS.

B) Rebound Resiliency

The shaping material (46) preferably has mechanical properties that demonstrate rebound resiliency. It is preferable that the shaping material (46) gives a cushioning effect, but not completely "bottom out" by being compressed to a two-dimensional structure.

C) Hardness

The shaping material (46) preferably has mechanical properties that demonstrate an appropriate amount of hardness. As stated above, the shaping material (46) preferably gives a cushioning effect. However, it is also preferable that the shaping material (46) gives some support to the foot area. It is preferred that the shaping material (46) has between about 1 to about 32 Hs – SRIS C.

D) Vertical Wicking Performance

The shaping material (46) preferably has mechanical properties that demonstrate vertical wicking performance. Vertical wicking performance is the ability of the shaping material (46) to transfer body liquids away from the surface of the skin into the shaping material (46).

E) Absorbent Capacity and Absorbent Capacity Under Pressure

The shaping material (46) preferably has mechanical properties that demonstrate absorbent capacity and absorbent capacity under pressure. Absorbent capacity is the total amount of test fluid which a given shaping material (46) sample will absorb into its structure per unit mass of solid material in the sample. Absorbent capacity under pressure refers to the amount of that

fluid held under no confining pressure (free capacity) that the shaping material (46) would retain within its structure when the sample is subjected to compressive force.

#### F) Vapor Permeability

The shaping material (46) preferably has mechanical properties that demonstrate vapor permeability. The shaping material (46) should have a MVTR at least 200 g/24 h/m<sup>2</sup>, preferably at least 400 g/24 h/m<sup>2</sup>, and most preferably at least 500 g/24 h/m<sup>2</sup> as described in TEST METHOD below.

If foam materials are used for the shaping material (46), such foam material can have a relatively open celled or a relatively closed celled character. The type of character depends upon whether and/or the extent to which, the cell walls or boundaries, i.e. the cell windows, are filled or taken up with material. For purposes of the present invention, a foam material in which about 80% of its cells which have intercellular openings or "windows" which are large enough to permit ready fluid transfer from one cell to the other within the foam structure are relatively open-celled foam structures. For purposes of the present invention, a foam material in which about 20% of its cells which have intercellular openings or "windows" which are large enough to permit ready fluid transfer from one cell to the other within the foam structure are relatively closed-celled foam structures.

#### ENCLOSING MATERIAL

The enclosing material (48) can be any material that was previously described in the adherent article (42) description above, specifically having a MVTR value of at least about 200 g/24 h/m<sup>2</sup>, preferably at least about 400 g/24 h/m<sup>2</sup>, and more preferably at least about 500 g/24 h/m<sup>2</sup>.

#### OTHER ELEMENTS

The present invention may optional comprise other elements that can benefit a user. Examples of such other elements include a moisture absorption layer that temporally retains the moisture and then allows water vapor to permeate out of the disposable self-adhesive foot patch; medicinal additives such as anti-fungal, anti-microbial, cooling or heating stimulating compounds and any combination thereof; malodor control such as deodorants, zeolite, perfumes and any combination thereof; compositions giving skin benefits such

as moisturizing lotions, niacinamide powder, callus softening compositions, corn removal composition, wart removal compositions, and any similar products; and massaging or other circulation benefits may be optionally included in the present invention; and any combination of the foregoing elements.

## TEST METHODS

### Moisture Vapor Transmission Rate

The Moisture Vapor Transmission Rate (MVTR) determines the amount of moisture adsorbed by calcium chloride in a "up" like container that is covered by a test specimen where the moisture source is a controlled temperature/humidity environment ( $40^{\circ}\pm.3^{\circ}\text{C}$ ./ $75.\pm.3\%$  relative humidity) separated from the calcium chloride by the test specimen.

The sample holding a cup is a cylinder with an inner diameter of 30 mm and an inside height from bottom to top flange of 49 mm. A flange having a circular opening to match the opening of the cylinder can be fixed by screws, and a silicone rubber sealing ring with an opening matching the inner diameter of the cup, fits between the top flange and the cylinder. The test specimen, in this case either the entire foot patch or the components of the foot patch taken individually, is positioned such that it covers the cylinder opening. The specimen is tightly fixed between the silicone rubber sealing and the upper flange of the cylinder so it acts as a barrier to moisture transport.

The equipment as well as the test specimen should be equilibrated to the temperature of the controlled environment prior to testing.

The absorbent desiccant material is calcium chloride, such as can be purchased from Wako Pure Chemical Industries Ltd., Richmond, Va. under the product designation 030-00525. If kept in a sealed bottle, it can be used directly. It also can be sieved to remove lumps, or excessive amounts of fines, if existing. It also can be dried at  $200^{\circ}\text{C}$ . for about 4 hours.

The calcium chloride is weighed ( $15.0.\pm.0.02$  g) into the cup, and tapped lightly so as to level it out, such that the surface is about 1 cm from the top of the cup.

A test sample, cut to about 3.2 cm by 6.25 cm, is placed flat and overlapping with the seal over the opening, and the seal and the top flange are affixed by the screws without over tightening. The total weight of the cup



assembly is accurately recorded to four decimal places, and the assembly is placed into the constant temperature/humidity chamber.

After 5 hours exposure to the test humidity (without opening of chamber), the sample is removed and immediately covered tightly with a non-vapor permeable plastic film such as SARAN WRAP. After cooling about 30 minutes to allow for temperature equilibration, the plastic film is removed and the assembly is reweighed.

The MVTR value is then calculated by determining the moisture increase over 5 hours due to transport through the 3 cm circular opening and converting the result to units of "g/24 h/m<sup>2</sup>".

For each test, three replicates should be run, the resulting values will be averaged, and the result rounded to the nearest 100 value.

Overall, this method is applicable to thin films, multi-layer laminates and the like. Experience has shown, that typical standard deviations range between 50 and 250 g/24 h/m<sup>2</sup> for averaged values of up to about 5000 g/24 h/m<sup>2</sup>.

#### Air Permeability

The air permeability is determined by measuring the time in which a standard volume of air is drawn through the test specimen at a constant pressure and temperature. This test is particularly suited to materials having relatively high permeability to gases, such as nonwovens, apertured films and the like.

The test is operated in a temperature and humidity controlled environment, at 22° ± 0.2°C. and 50. ± 2% relative humidity. The test specimen has to be conditioned for at least 2 hours.

Suitable test equipment is manufactured by Hoppe & Schneider GmbH, Heidelberg, Germany, under the designation "Textiluhr nach Kretschmar". The apparatus is essentially a bellows in a vertical arrangement, with its upper end being mounted in a fixed position, and the lower end being releasably held at its upper position, which can be loosened by means of a release handle to slide under controlled conditions to the lower position, thereby increasing the volume inside the bellows by pulling air through the test specimen which covers the air inlet opening at the upper end of the bellows. The test specimen is firmly held to cover the air inlet opening by means of a fastening ring having an area of either 5 cm<sup>2</sup> or 10 cm<sup>2</sup> (allows for different samples sizes and/or different permeability ranges). If the 10 cm<sup>2</sup> ring is used, the sample should be at least 55 mm wide,

for the 5 cm<sup>2</sup> ring a sample width of at least 35 mm is required. For both, the samples should have a length of about 150 mm.

Optionally, the sample holding device can comprise a stretching element, such as to enable measurement of elastic materials under stretched conditions.

The equipment comprises a stopwatch (1/100 sec increments) which automatically measures the time between the operation of the release handle, which starts the sliding of the bellows, and the bottom of the bellows reaching its lower or stop position.

The air permeability of the material can then be calculated by dividing a constant (provided by the supplier for each individual test apparatus; K is about 200.000 for a tested area of 5 cm<sup>2</sup>, and about 400.000 for an area of 10 cm<sup>2</sup>) by the time as measured in seconds, resulting in units of: liters/cm<sup>2</sup> /sec. The test is repeated once for each test sample, and should be repeated on 10 samples to provide a representative value for a material.

An example of the invention set forth hereinafter is by way of illustration and is not intended to be in any way limiting of the invention.

#### EXAMPLE 1

The disposable self-adhesive foot patch in Figs. 2 and 3 are intended for use as a longitudinal arch support. The adhesive article (42, 142) and enclosing material (48) comprises brown body tape sold under the tradename KINESHIO TAPE or KINESIO TEX by Kineshio K.K. Japan. The adhesive of the KINESHIO TAPW is an acrylic synthetic-resin and is intermittently applied in 2 mm strips separated by 1 mm non-coated strips. The resilient ridge (44) is a silicone tube. The shaping material (46) is abrasion resistant styrene based foam that is described in WO 98/05814. A zeolite sheet is added for deodorant purposes and niacinamide powder is added for skin care benefits.

It is understood that the example given above is by way of illustration and is not intended to be in any way limiting.

## WHAT IS CLAIMED IS:

1. A disposable self-adhesive foot patch comprising:
  - (a) an adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g}/24 \text{ h}/\text{m}^2$ ; the first side of the adherent article being provided with an adhesive; and
  - (b) a resilient ridge having an elongated shape with a major and a minor axis, the resilient ridge being connected to the second side of the adherent article;wherein first side of the adherent article is placed against the midfoot area and adhered thereto by the adhesive.
2. A disposable self-adhesive foot patch comprising:
  - (a) an adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g}/24 \text{ h}/\text{m}^2$ ; the first side of the adherent article being provided with an adhesive; and
  - (b) a resilient ridge having an elongated shape with a major and a minor axis superposed over the first side of the adherent article;wherein the resilient ridge is placed against the midfoot area and adhered thereto by the adhesive provided on the first side of the adherent article.
3. The disposable self-adhesive foot patch of Claim 1 or Claim 2 wherein the disposable self-adhesive foot patch further comprises a shaping material superposed over the resilient ridge.
4. The disposable self-adhesive foot patch of Claim 3 wherein the disposable self-adhesive foot patch further comprises an enclosing material superposed over the shaping material and the enclosing material being attached to the first side of the adherent article.
5. The disposable self-adhesive foot patch of Claim 3 wherein the disposable self-adhesive foot patch further comprises an enclosing material that is engaged with the shaping material and the enclosing material being attached to the second side of the adherent article.

6. The disposable self-adhesive foot patch of Claim 1 or Claim 2 wherein the adherent article, the resilient ridge, the shaping material, the enclosing material, or any combination thereof is clear or skin-toned in appearance.
7. The disposable self-adhesive foot patch of Claim 1 further comprising a liquid absorption layer, medicinal additives, malodor control additives, skin care compositions, massaging features, or any combinations thereof.
8. A disposable self-adhesive foot patch comprising:
  - (a) an adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g/24 h/m}^2$ ; the first side of the adherent article being provided with an adhesive;
  - (b) a resilient ridge having an elongated structure with a major and minor axis, the resilient ridge being superposed over the second side of the adherent article, wherein the resilient ridge is comprised of one or more material;
  - (c) a shaping material superposed over the resilient ridge wherein the shaping material comprises one or more materials;
  - (d) an enclosing material, with a MVTR value of at least  $200 \text{ g/24 h/m}^2$ ; wherein the enclosing material superposes over the shaping material and connects to the second side of the adherent article;wherein first side of the adherent article is placed against the midfoot area.
9. A disposable self-adhesive foot patch comprising:
  - (a) a adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g/24 h/m}^2$ ; the first side of the adherent article being provided with an adhesive
  - (b) a resilient ridge having an elongated structure with a major and minor axis, the resilient ridge being superposed over the second side of the adherent article and the resilient ridge is comprised of one or more material;
  - (c) a shaping material superposed over the resilient ridge wherein the shaping material comprises one or more materials;

(d) an enclosing material, with a MVTR value of at least 200 g/24 h/m<sup>2</sup>;  
wherein the enclosing adherent article superpose over the shaping  
material and connects to the second side of the adherent article;  
wherein the resilient ridge is placed against the midfoot area and adhered  
thereto by the adhesive provided on the first side of the adherent article.

**AMENDED CLAIMS**

[received by the International Bureau on 21 March 2002 (21.03.02);  
original claims 1-9 replaced by new claims 1-10 (3 pages)]

1. A disposable self-adhesive foot patch comprising:
  - (a) an adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g}/24 \text{ h}/\text{m}^2$ ; the first side of the adherent article being provided with an adhesive; and
  - (b) a resilient ridge having an elongated shape with a major and a minor axis, the resilient ridge being connected to the second side of the adherent article;wherein first side of the adherent article is placed against the midfoot area and adhered thereto by the adhesive.
2. A disposable self-adhesive foot patch comprising:
  - (a) an adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g}/24 \text{ h}/\text{m}^2$ ; the first side of the adherent article being provided with an adhesive; and
  - (b) a resilient ridge having an elongated shape with a major and a minor axis superposed over the first side of the adherent article;wherein the resilient ridge is placed against the midfoot area and adhered thereto by the adhesive provided on the first side of the adherent article.
3. The disposable self-adhesive foot patch of Claim 1 or Claim 2 wherein the disposable self-adhesive foot patch further comprises a shaping material superposed over the resilient ridge.
4. The disposable self-adhesive foot patch of Claim 3 wherein the disposable self-adhesive foot patch further comprises an enclosing material superposed over the shaping material and the enclosing material being attached to the first side of the adherent article.
5. The disposable self-adhesive foot patch of Claim 3 wherein the disposable self-adhesive foot patch further comprises an enclosing material that is engaged with the shaping material and the enclosing material being attached to the second side of the adherent article.

6. The disposable self-adhesive foot patch of Claim 1 or Claim 2 wherein the adherent article, the resilient ridge, the shaping material, the enclosing material, or any combination thereof is clear or skin-toned in appearance.
7. The disposable self-adhesive foot patch of Claim 1 further comprising a liquid absorption layer, medicinal additives, malodor control additives, skin care compositions, massaging features, or any combinations thereof.
8. A disposable self-adhesive foot patch comprising:
  - (a) an adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g}/24 \text{ h}/\text{m}^2$ ; the first side of the adherent article being provided with an adhesive;
  - (b) a resilient ridge having an elongated structure with a major and minor axis, the resilient ridge being superposed over the second side of the adherent article, wherein the resilient ridge is comprised of one or more material;
  - (c) a shaping material superposed over the resilient ridge wherein the shaping material comprises one or more materials;
  - (d) an enclosing material, with a MVTR value of at least  $200 \text{ g}/24 \text{ h}/\text{m}^2$ ; wherein the enclosing material superposes over the shaping material and connects to the second side of the adherent article;wherein first side of the adherent article is placed against the midfoot area.
9. A disposable self-adhesive foot patch comprising:
  - (a) a adherent article having a first side and second side wherein the adherent article has an MVTR value of at least  $200 \text{ g}/24 \text{ h}/\text{m}^2$ ; the first side of the adherent article being provided with an adhesive
  - (b) a resilient ridge having an elongated structure with a major and minor axis, the resilient ridge being superposed over the second side of the adherent article and the resilient ridge is comprised of one or more material;
  - (c) a shaping material superposed over the resilient ridge wherein the shaping material comprises one or more materials;

(d) an enclosing material, with a MVTR value of at least 200 g/24 h/m<sup>2</sup>; wherein the enclosing adherent article superpose over the shaping material and connects to the second side of the adherent article; wherein the resilient ridge is placed against the midfoot area and adhered thereto by the adhesive provided on the first side of the adherent article.

10. A method of preventing fatigue in the foot and leg area which comprises the step of applying the disposable self-adhesive foot patch of Claim 1 or Claim 2 to the midfoot area.



1/2

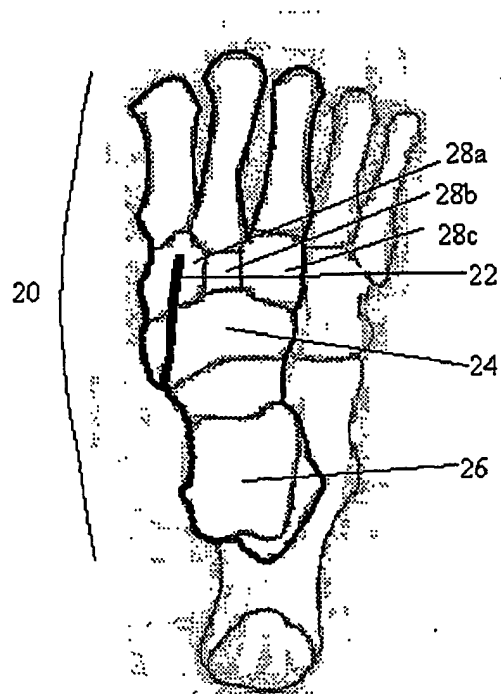


Fig. 1

2/2

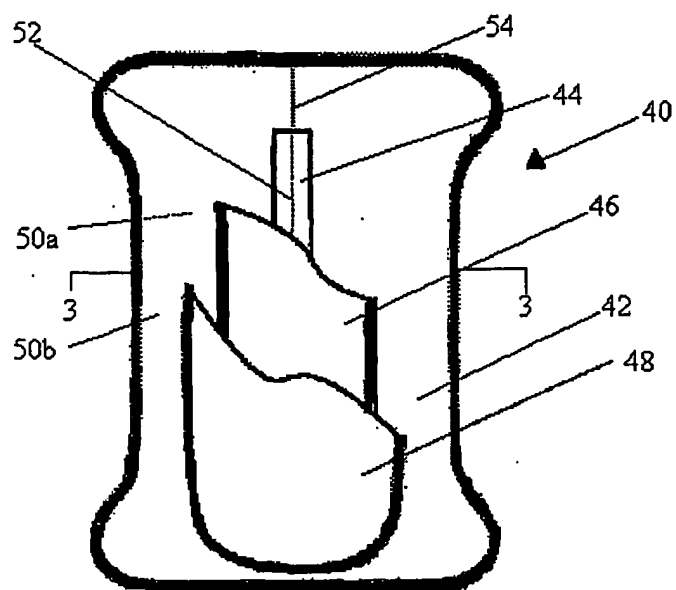


Fig. 2

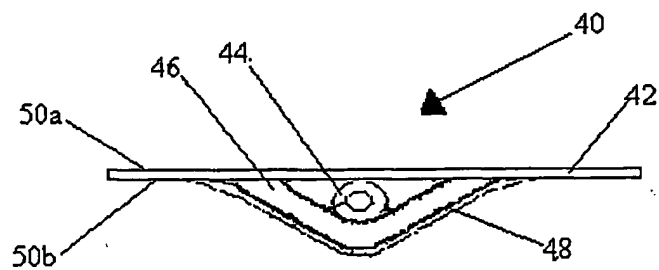


Fig. 3

# INTERNATIONAL SEARCH REPORT

Int'l Application No  
PC 1/US 01/17718

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 A43B7/14 A43B17/10 A43B7/06 A61F13/06		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC 7 A43B A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 120 473 A (OLIVERIO CATHERINE H) 19 September 2000 (2000-09-19) cited in the application the whole document	1-9
A	GB 2 242 607 A (WARE SHELIA MARY) 9 October 1991 (1991-10-09) the whole document	1-9
A	WO 97 37624 A (ROSSI FRANCESCA ; GAME INT SA (PA)) 16 October 1997 (1997-10-16) the whole document	1-9
A	US 2 253 429 A (HESS ROGER L) 19 August 1941 (1941-08-19) the whole document	1-9
<input type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search 10 January 2002		Date of mailing of the international search report 21/01/2002
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Claude1, B

# INTERNATIONAL SEARCH REPORT

Int. I Application No  
PCT/US 01/17718

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6120473	A	19-09-2000	NONE	
GB 2242607	A	09-10-1991	NONE	
WO 9737624	A	16-10-1997	IT M0960044 A1 AU 2306597 A WO 9737624 A1	06-10-1997 29-10-1997 16-10-1997
US 2253429	A	19-08-1941	NONE	